REMARKS

Claims 1-6, 8, 10-11, 24 and 33-37 were examined. Claims 4, 8, 10-11, 24 and 35 are amended. Claims 1-6, 8, 10-11, 24 and 33-37 remain in the Application.

The Patent Office rejects claims 1, 5-6, 8, 24 and 36-37 under 35 U.S.C. §102(e). The Patent Office rejects claims 2-4, 10-11 and 33-34 under 35 U.S.C. §103(a). Reconsideration of the pending claims is respectfully requested in view of the above amendments and the following remarks.

A. Correction to Drawings

Applicant submits herewith a corrected drawing sheet 1 (Figure 1) and drawing sheet 2 (Figure 2). The corrected drawing sheets include reference numeral 27 that references a vessel surface of vessel 7. Vessel surface 27 is described in the Application at paragraph [0041]. Vessel surface 27 is also shown in Figure 3. Applicant respectfully requests that the Patent Office accept the substituted drawings.

B. After Final Claim Amendments

Applicant amends claims 4, 10-11, 24 and 35. The amendments are intended to correct typographic or otherwise non-substantive deficiencies with respect to the amended claims. Applicant respectfully requests that the Patent Office enter the amendments to the claims.

C. 35 U.S.C. §102(e): Rejection of Claims 1, 5-6, 8, 24 & 36-37

The Patent Office rejects claims 1, 5-6, 8, 24 and 36-37 under 35 U.S.C. §102(e) as anticipated by U.S. Patent No. 6,048,332 of Duffy (Duffy). Duffy discloses systems and methods using a drug delivery catheter that includes a porous balloon mounted onto the distal end of the catheter. See Abstract. The systems and methods may deliver a treatment agent to an inner or luminal surface of a body lumen or deliver a treatment agent that may be carried to other locations within the body to provide treatment to areas larger than or distant from the areas of tissue contact. See col. 4, lines 46-56.

Duffy also describes systems and methods that can be used to introduce a treatment agent following techniques intended to dilate stenotic regions of a body lumen or other techniques to treat localized lesions of a body lumen. See col. 12, lines 5-8. "For example, a stenotic region of a blood vessel 84 can be stretched using the techniques of balloon dilation and can thereupon be treated with the methods and systems described herein. As another example, drug delivery according to these methods can be applied following procedures such as angioplasty, atherotomy, atherectomy and stent placement." Col. 12, lines 18-24.

Claim 1 describes a method comprising injuring a vessel region where the vessel region comprises a bypass vessel. The bypass vessel is adjacent to a primary vessel leading to a target area for blood flow. The method also provides delivering an arteriogenic factor to the bypass vessel in a medically effective manner structurally to enlarge an existing blood vessel.

Independent claim 1 is not anticipated by Duffy, because Duffy does not describe injuring a vessel region that comprises a bypass vessel adjacent to a primary vessel leading to a target area for blood flow. Duffy describes introducing a catheter with a porous balloon into a blood vessel. Duffy does not say anything about introducing its device or delivering a treatment agent into a vessel that comprises a bypass vessel adjacent to a primary vessel leading to a target area of blood flow. Duffy does describe systems and methods for use following techniques to dilate a stenotic region of a blood vessel. In this context, Duffy is describing treating the blood vessel containing the stenosis, not a bypass vessel.

Claim 1 is also not anticipated by Duffy, because Duffy does not describe delivering an arteriogenic factor to a bypass vessel. Applicant is unable to find any discussion in Duffy relating to potential treatment agents or drugs that might be arteriogenic factors or the delivery of arteriogenic factors through the described devices. In dilation cases referenced by Duffy, the stenotic region in a blood vessel is stretched or dilated by a device and/or method separate from Duffy. Duffy merely follows such dilation.

The Patent Office opines "that the delivery of an arteriogenic factor to a vessel region would result in the arteriogenic factor being supplied to the primary vessel and any bypass vessel in the region." See Office Action mailed August 10, 2006, page 2. Such an opinion has no basis in the facts before the Patent Office with regard to the application of the cited art. Applicant

therefore believes the Patent Office is taking official notice of facts not of record and requests the Patent Office support its opinion or withdraw it. Official notice, unsupported by documentary evidence, should only be taken by the Patent Office where the fact asserted is well known, or is common knowledge in the art, capable of instant and unquestionable demonstration as being well known. See MPEP 2144.03.

The Patent Office also opines that "the delivery of an arteriogenic factor would inherently damage the vessel region, even if only minimally." See Office Action, page 4. Again, there is no basis for such a conclusion or opinion. For example, it is entirely possible to deliver an arteriogenic factor into a blood vessel through a delivery mechanism where a delivery device did not touch the luminal surface of the blood vessel where the arteriogenic factor is delivered. One way is centering a delivery lumen of a catheter in a blood vessel upstream of the target vessel region. Another way is simply a systemic delivery of an arteriogenic agent, such as an injection of an arteriogenic agent distal to the vessel region with the intention that the arteriogenic factor will be carried in the blood stream to the vessel region.

The Patent Office is also of the opinion that in all likelihood the vessel region was injured previously "hence the need of the arteriogenic factor of Duffy." See Office Action, page 4. Again, there is no basis in fact for the opinion or conclusion that a vessel region including a bypass vessel is previously injured. Claim 1 is addressing an "injury" or occlusion in a primary vessel through acts directed at a bypass vessel. Such a statement by the Patent Office also misunderstands an object of the invention's claim 1. It is appreciated that, in one embodiment, delivery of an arteriogenic factor to a bypass vessel may structurally enlarge the bypass vessel or another vessel thereby allowing blood flow to bypass a primary vessel in route to a target area. Injuring of the bypass vessel along with delivery of an arteriogenic factor will accelerate the structural enlargement of the bypass vessel or another vessel. Thus, in one aspect, a bypass vessel is injured to accelerate arteriogenisis. Applicant respectfully requests that the Patent Office withdraw its opinion or support it with a refernce.

Finally, the Patent Office states that "[t]he patent by Duffy therefore shows the same structure as is claimed, and should be expected to achieve the same results." See Office Action, page 4. Applicant notes that the pending claims are directed to a method and not a structure,

therefore any similarity in structure between what is described in the Application and Duffy is irrelevant.

Claims 5-6 and 8 depend from claim 1 and therefore contain all the limitations of the claim. For at least the reasons stated with respect to claim 1, claims 5-6 and 8 are not anticipated by Duffy.

Independent claim 24 describes a method of structurally enlarging a bypass vessel adjacent to a primary vessel. The method comprises: injuring a bypass vessel; advancing a distal portion of a catheter to the bypass vessel; delivering an arteriogenic factor to the bypass vessel via the catheter; and causing an enlargement to at least a portion of the bypass vessel.

As noted above, with respect to claim 1, Duffy does not describe injuring a bypass vessel adjacent to a primary vessel; advancing a distal portion of a catheter to the bypass vessel; or delivering an arteriogenic factor to the bypass vessel. Further, Duffy does not describe causing an enlargement to at least a portion of the bypass vessel.

Claims 36 and 37 depend from claim 24 and contains all the limitations of that claim. For at least the reasons stated with respect to claim 24, claims 36 and 37 are not anticipated by Duffy.

Applicant respectfully requests that the Patent Office withdraw the rejection to claims 1, 5-6, 8, 24 and 36-37 under 35 U.S.C. §102(e).

D. 35 U.S.C. 103(a): Rejection of Claims 2-4, 10-11 & 34-35

The Patent Office claims 2-4, 10-11 and 34-35 under 35 U.S.C. §103(a) as obvious over Duffy. Claims 2-4 and 10-11 depend from claim 1 and therefore contain all the limitations of that claim. For the reasons stated above with respect to independent claim 1, claims 2-4 and 10-11 are not obvious over Duffy. Duffy fails to teach or provide any motivation for injuring a vessel region comprising a bypass vessel adjacent to a primary vessel or delivering an arteriogenic factor to the bypass vessel.

In addition, with respect to claim 2, Duffy does not teach or provide any motivation for delivering an arteriogenic factor for a duration ranging from about one week to about five weeks. With respect to claim 3, Duffy does not teach or provide any motivation for providing a second delivery of an arteriogenic factor to a vessel region at about three to about ten days following a delivery. With respect to claim 4, Duffy does not teach or provide any motivation for advancing an arteriogenic factor from a syringe to a vessel region. With respect to claim 10, Duffy does not teach or provide any motivation for delivering an arteriogenic factor by a catheter with a distal portion cooled to about 0°C and about 10°C. With respect to claim 11, Duffy does not teach or provide any motivation for delivering an arteriogenic factor by a catheter with a distal portion heated to a range from about 40°C to about 90°C.

Claims 33-35 depend from claim 24 and therefore contain all the limitations of that claim. For the reasons stated with respect to claim 24, claims 33-35 are not obvious over Duffy. Duffy does not teach or provide any motivation for injuring a bypass vessel adjacent to a primary vessel; advancing a distal portion of a catheter to the bypass vessel; or delivering an arteriogenic factor to the bypass vessel.

In addition, with respect to claim 33, Duffy also does not teach or provide any motivation for providing an arteriogenic factor to a bypass vessel for a duration from about one week to about five weeks. With respect to claim 34, Duffy does not teach or provide any motivation for providing a second delivery of an arteriogenic factor to a bypass vessel at about 3 to about 10 days after a delivery of an arteriogenic factor. With respect to claim 35, Duffy also does not teach or provide any motivation for advancing an arteriogenic factor from a syringe to a bypass vessel.

For the above stated reasons, Applicant respectfully requests that the Patent Office withdraw the rejection to claims 2-4, 10-11 and 34-35 under 35 U.S.C. §103(a).

CONCLUSION

In view of the foregoing, it is believed that all claims now pending patentably define the subject invention over the prior art of record and are in condition for allowance and such action is earnestly solicited at the earliest possible date.

If necessary, the Commissioner is hereby authorized in this, concurrent and future replies, to charge payment or credit any overpayment to Deposit Account No. 02-2666 for any additional fees required under 37 C.F.R. §§ 1.16 or 1.17, particularly extension of time fees.

Respectfully submitted,

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CERTIFICATE OF TRANSMISSION

I hereby certify that this correspondence is being submitted electronically via EFS Web on the date shown below to the United States Patent and Trademark Office.

Nedy Calderon 9/29/06

Nedy Calderon Date